

We claim:

1. A recombinant expression vector comprising a first nucleic acid having the sequence AGGAGGGTTTTCAT operatively linked to a second nucleic acid comprising three domains, wherein said first domain has a nucleotide sequence which encodes amino acids 1-225 of an HIV p24 antigen, said second domain has a nucleotide sequence which encodes an HIV gp41 antigen or an antigenic fragment of said HIV gp41 antigen and said third domain has a nucleotide sequence which encodes amino acids 224 to 232 of an HIV p24 antigen.
- 10 2. The vector of Claim 1, wherein said vector is pGEX7 comprising said first nucleic and second nucleic acids.
- 15 3. The vector of Claim 1, wherein said first, second and third domains together encode amino acids 1-258 of SEQ ID NO:2.
4. The vector of Claim 3, wherein said vector is pGEXp24gp41-ANT.
5. The vector of Claim 1, wherein said first, second and third domains together encode amino acids 1-258 of SEQ ID NO:4.
- 20 6. The vector of Claim 5, wherein said vector is pGEXp24gp41-MVP.
7. The vector of Claim 1, wherein said first, second and third domains together encode amino acids 1-258 of SEQ ID NO:6.
8. The vector of Claim 7, wherein said vector is pGEXp24gp41-X84328.
- 25 9. A prokaryotic host cell comprising an expression vector of any one of Claims 3, 5 or 7.
10. A method of producing an HIV p24-gp41 antigen, which comprises
 - (a) treating a host cell comprising an expression vector of any one of Claims 3, 5 or 7 under conditions and for a time effective to express said antigen; and
 - (b) recovering said antigen.
- 30 11. A recombinant HIV p24-gp41 antigen produced by the method of Claim 10.

5 12. A composition comprising the recombinant HIV p24-gp41 antigen of
Claim 11, wherein said composition is essentially free of prokaryotic antigens and
other HCV-related proteins.

10 13. A diagnostic system, in kit form, comprising, in an amount sufficient to
perform at least one assay, the composition of an HIV p24-gp41 antigen according to
Claim 12.

15 14. The diagnostic system according to Claim 13, wherein said HIV p24-gp41
antigen is affixed to a solid matrix.

20 15. A method of assaying a body fluid sample for the presence of antibodies
against an HIV p24-gp41 antigen which comprises:

25 a) forming an immunoreaction admixture by admixing said body fluid
sample with a composition of Claim 12;
b) maintaining said immunoreaction admixture for a time period sufficient
for any of said antibodies present to immunoreact with said antigen to
form an immunoreaction product; and
c) detecting the presence of any of said immunoreaction product formed
and thereby the presence of said antibodies.

30 16. The method of Claim 15, wherein said detecting in step (c) comprises the
steps of:
25 (i) admixing said immunoreaction product formed in step (c) with a labeled
specific binding agent to form a labeling admixture, said labeled specific
binding agent comprising a specific binding agent and a label;
35 (ii) maintaining said labeling admixture for a time period sufficient for any
of said immunoreaction product present to bind with said labeled
specific binding agent to form a labeled product; and
 (iii) detecting the presence of any of said labeled product formed, and
 thereby the presence of said immunoreaction product.

30 17. The method of Claim 16, wherein said specific binding agent is Protein A
or at least one of the antibodies anti-human IgG and anti-human IgM.

35 18. The method of Claim 16, wherein said label is a lanthanide chelate, biotin,
an enzyme or radioactive isotope.

5 19. A recombinant expression vector comprising a first nucleic acid having the sequence AGGAGGGTTTCAT operatively linked to a second nucleic acid consisting of a nucleotide sequence which encodes amino acids 1-120 of an HCV capsid antigen.

10 20. The vector of Claim 19, wherein said vector is pGEX7 comprising said first nucleic and second nucleic acids.

15 21. The vector of Claim 19, wherein said amino acids are amino acids 1-120 of SEQ ID NO:8.

20 22. The vector of Claim 21, wherein said vector is pGEX-C120H-V68.

25 23. The vector of Claim 19, wherein said amino acids are amino acids 1-120 of SEQ ID NO:10.

30 24. The vector of Claim 23, wherein said vector is pGEX-C120H.

35 25. The vector of Claim 19, wherein said amino acids are amino acids 1-120 of SEQ ID NO:12.

40 26. The vector of Claim 25, wherein said vector is pGEX-C120H-ISO2.

45 27. The vector of Claim 19, wherein said amino acids are amino acids 1-120 of SEQ ID NO:14.

50 28. The vector of Claim 27, wherein said vector is pGEX-C120H-ISO3.

55 29. A prokaryotic host cell comprising an expression vector of any one of Claims 19, 21, 23, 25 or 27.

60 30. A method of producing an HCV capsid antigen consisting of amino acid residues 1-120 which comprises

65 (a) treating a host cell comprising an expression vector of any one of Claims 19, 21, 23, 25 or 27 under conditions and for a time effective to express said antigen; and

70 (b) recovering said antigen.

75 31. A recombinant HCV capsid antigen produced by the method of Claim 30.

80 32. A composition comprising a recombinant HCV capsid antigen of Claim 31, wherein said composition is essentially free of prokaryotic antigens and other HCV-related proteins.

5 33. A diagnostic system, in kit form, comprising, in an amount sufficient to perform at least one assay, the composition of an HCV capsid antigen according to Claim 32.

10 34. The diagnostic system according to Claim 33, wherein said HCV structural protein is affixed to a solid matrix.

15 35. A method of assaying a body fluid sample for the presence of antibodies against an HCV capsid antigen which comprises:

- a) forming an immunoreaction admixture by admixing said body fluid sample with a composition of Claim 32;
- b) maintaining said immunoreaction admixture for a time period sufficient for any of said antibodies present to immunoreact with said HCV capsid antigen to form an immunoreaction product; and
- c) detecting the presence of any of said immunoreaction product formed and thereby the presence of said antibodies.

20 36. The method of Claim 35, wherein said detecting in step (c) comprises the steps of:

- (i) admixing said immunoreaction product formed in step (c) with a labeled specific binding agent to form a labeling admixture, said labeled specific binding agent comprising a specific binding agent and a label;
- (ii) maintaining said labeling admixture for a time period sufficient for any of said immunoreaction product present to bind with said labeled specific binding agent to form a labeled product; and
- (iii) detecting the presence of any of said labeled product formed, and thereby the presence of said immunoreaction product.

25 37. The method of Claim 36, wherein said specific binding agent is Protein A or at least one of the antibodies anti-human IgG and anti-human IgM.

30 38. The method of Claim 36, wherein said label is a lanthanide chelate, biotin, an enzyme, or a radioactive isotope.

35 39. A recombinant expression vector comprising a first nucleic acid having the sequence AGGAGGGTTTCAT operatively linked to a second nucleic acid consisting of a nucleotide sequence which encodes an HCV nonstructural 794 antigen

5 having the amino acid sequence of SEQ ID NO:16 or the corresponding sequence from another HCV strain.

40. The vector of Claim 39, wherein said expression vector is pGEX7 comprising said first nucleic and second nucleic acids.

41. The vector of Claim 40, wherein said vector is pGEX-NS3-794.

10 42. A prokaryotic host cell comprising an expression vector of Claim 39.

43. A method of producing an HCV nonstructural 794 antigen which comprises

(a) treating a host cell comprising an expression vector of Claim 39 under conditions and for a time effective to express said antigen; and

15 (b) recovering said antigen.

44. A recombinant HCV nonstructural 794 antigen produced by the method of Claim 43.

45. A composition comprising the recombinant HCV nonstructural 794 antigen of Claim 44, wherein said composition is essentially free of prokaryotic 20 antigens and other HCV-related proteins.

46. A diagnostic system, in kit form, comprising, in an amount sufficient to perform at least one assay, the composition of an HCV nonstructural 794 antigen according to Claim 45.

25 47. The diagnostic system according to Claim 46, wherein said HCV nonstructural 794 antigen is affixed to a solid matrix.

48. A method of assaying a body fluid sample for the presence of antibodies against an HCV nonstructural 794 antigen which comprises:

30 a) forming an immunoreaction admixture by admixing said body fluid sample with a composition of Claim 45;

b) maintaining said immunoreaction admixture for a time period sufficient for any of said antibodies present to immunoreact with said HCV nonstructural 794 antigen to form an immunoreaction product; and

c) detecting the presence of any of said immunoreaction product formed and thereby the presence of said antibodies.

5 49. The method of Claim 48, wherein said detecting in step (c) comprises the steps of:

- (i) admixing said immunoreaction product formed in step (c) with a labeled specific binding agent to form a labeling admixture, said labeled specific binding agent comprising a specific binding agent and a label;
- (ii) maintaining said labeling admixture for a time period sufficient for any of said immunoreaction product present to bind with said labeled specific binding agent to form a labeled product; and
- (iii) detecting the presence of any of said labeled product formed, and thereby the presence of said immunoreaction product.

10 50. The method of Claim 49, wherein said specific binding agent is Protein A on at least one of the antibodies anti-human IgG and anti-human IgM.

15 51. The method of Claim 49, wherein said label is a lanthanide chelate, biotin, an enzyme, or a radioactive isotope.

20 52. A recombinant expression vector comprising a first nucleic acid having the sequence AGGAGGGTTTCAT operatively linked to a second nucleic acid consisting of a nucleotide sequence which encodes a CAP-B antigen having the amino acid sequence of SEQ ID NO:18 or the corresponding sequence from another HCV strain.

25 53. The vector of Claim 52, wherein said expression vector is pGEX7 comprising said first nucleic and second nucleic acids.

 54. The vector of Claim 53, wherein said vector is pGEX-CAP-B.

 55. A prokaryotic host cell comprising an expression vector of Claim 52.

 56. A method of producing an HCV CAP-B antigen which comprises

- (a) treating a host cell comprising an expression vector of Claim 52 under conditions and for a time effective to express said antigen; and
- (b) recovering said antigen.

 57. A recombinant HCV CAP-B antigen produced by the method of Claim 56.

 58. A composition comprising the recombinant HCV CAP-B antigen of Claim 57, wherein said composition is essentially free of prokaryotic antigens and other HCV-related proteins.

5 59. A diagnostic system, in kit form, comprising, in an amount sufficient to perform at least one assay, the composition of an HCV CAP-B antigen according to Claim 58.

60. The diagnostic system according to Claim 59, wherein said HCV CAP-B antigen is affixed to a solid matrix.

10 61. A method of assaying a body fluid sample for the presence of antibodies against an HCV CAP-B antigen which comprises:

- a) forming an immunoreaction admixture by admixing said body fluid sample with a composition of Claim 58;
- b) maintaining said immunoreaction admixture for a time period sufficient for any of said antibodies present to immunoreact with said HCV CAP-B antigen to form an immunoreaction product; and
- c) detecting the presence of any of said immunoreaction product formed and thereby the presence of said antibodies.

20 62. The method of Claim 61, wherein said detecting in step (c) comprises the steps of:

- (i) admixing said immunoreaction product formed in step (c) with a labeled specific binding agent to form a labeling admixture, said labeled specific binding agent comprising a specific binding agent and a label;
- (ii) maintaining said labeling admixture for a time period sufficient for any of said immunoreaction product present to bind with said labeled specific binding agent to form a labeled product; and
- (iii) detecting the presence of any of said labeled product formed, and thereby the presence of said immunoreaction product.

25 63. The method of Claim 62, wherein said specific binding agent is Protein A, or at least one of the antibodies anti-human IgG and anti-human IgM.

30 64. The method of Claim 62, wherein said label is a lanthanide chelate, a biotin, an enzyme, or a radioactive isotope.

35 65. A composition comprising a recombinant HCV capsid antigen consisting of amino acids 1-120 and a recombinant HCV nonstructural 794 antigen consisting of amino acids of SEQ ID NO:16 or the corresponding sequence from another HCV

5 strain, wherein said composition is essentially free of prokaryotic antigens and other HCV-related proteins.

66. The composition of Claim 65 wherein said recombinant HCV capsid antigen consists of amino acids 1-120 of SEQ ID NO:8.

10 67. The composition of Claim 65 wherein said recombinant HCV nonstructural 794 antigen consists of amino acids of SEQ ID NO: 16.

68. The composition of Claim 66 wherein said recombinant HCV nonstructural 794 antigen consists of amino acids of SEQ ID NO: 16.

15 69. The composition of Claim 65, wherein the ratio by weight of said capsid antigen to said nonstructural antigen is in a range of about 8:1 to about 1:1.

70. The composition of Claim 68, wherein the ratio by weight of said capsid antigen to said nonstructural antigen is in a range of about 8:1 to about 1:1.

71. A diagnostic system, in kit form, comprising, in an amount sufficient to perform at least one assay, the composition of any one of Claims 65, 68, 69 or 70.

20 72. The diagnostic system according to Claim 71, wherein said HCV capsid antigen and said HCV nonstructural 794 antigen are affixed to a solid matrix.

73. A method of assaying a body fluid sample for the presence of antibodies against an HCV capsid antigen or an HCV nonstructural antigen, which method comprises:

25 a) forming an immunoreaction admixture by admixing said body fluid sample with a composition of any one of Claims 65, 68, 69 or 70;

b) maintaining said immunoreaction admixture for a time period sufficient for any of said antibodies present to immunoreact with one or more of said antigens to form an immunoreaction product; and

c) detecting the presence of any of said immunoreaction product formed and thereby the presence of said antibodies.

30 74. The method of Claim 73, wherein said detecting in step (c) comprises the steps of:

35 (i) admixing said immunoreaction product formed in step (c) with a labeled specific binding agent to form a labeling admixture, said labeled specific binding agent comprising a specific binding agent and a label;

5 (ii) maintaining said labeling admixture for a time period sufficient for any of said immunoreaction product present to bind with said labeled specific binding agent to form a labeled product; and

(iii) detecting the presence of any of said labeled product formed, and thereby the presence of said immunoreaction product.

10 75. The method of Claim 74, wherein said specific binding agent is Protein at
least one of the antibodies anti-human IgG and anti-human IgM.

76. The method of Claim 74, wherein said label is a lanthanide chelate, biotin, an enzyme, or a radioactive isotope.